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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,566	03/23/2001	Stacey J. Bell	3037.1004-001	6492

21005 7590 02/10/2003

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EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 02/10/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,566

Applicant(s)

BELL ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14 and 19-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14 and 19-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to paper # 9A, received 11/22/02, which canceled claims 1-13 and 15-18, amended claim 14 and added new claims 19-41.

Upon further consideration, the rejection of claim 14 under 35 USC 112, second paragraph is withdrawn.

Regarding the rejection of claim 14 under 35 USC 102 (b) and (e), applicant's arguments were found persuasive and the rejection is withdrawn.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 32, 34, and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for carbohydrate, protein, fat and 5-hydroxytryptophan as an aid in the relief of symptomology associated with stress, does not reasonably provide enablement for caffeine as an aid in the relief of symptomology associated with stress. The specification does

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not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988)). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the

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following reasons:

The nature of the invention: The invention is drawn to a nutritional supplement that aids in the relief of symptomology associated with stress resulting from serotonin-deficient disorders.

The state of the prior art and the predictability or lack thereof in the art: The prior art shows caffeine used to increase cognitive performance, see Durlach, "The effects of a low dose of caffeine on cognitive performance" Psychopharmacology, 1998, vol 140, pp. 116-119 and Marriot, "Food components to enhance performance" National academy press, 1994, pp. 47-61. The prior art does not teach caffeine as an aid in the relief of symptomology associated with stress resulting from serotonin-deficient disorders.

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991).

In the instant specification, page 10, line 17 recites caffeine has been shown to improve long-term cognitive performance. The instant specification fails to teach caffeine as an aid in the relief of symptomology associated with stress resulting from serotonin-deficient disorders. The absence of working examples in the instant specification also fails to teach the use of caffeine in the relief of symptomology associated with stress resulting from serotonin-deficient disorders.

The quantity of experimentation needed:

The quantity of experimentation needed to determine if caffeine would aid in the relief of

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symptomology associated with stress resulting from serotonin-deficient disorders is undue.

Claims 19-31, 33, 35, and 37-41 are included in this rejection for depending upon rejected claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 19, 21, 23-26, 28, 30, and 32-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell (USPN 5,968,896) in view of Pollack (USPN 4,853,377).

The claimed invention is drawn a nutritional supplementation comprising a low-glycemic-index carbohydrate from about 1 to about 100 grams, protein comprising alpha lactalbumin-enriched whey protein from about 1 to about 100 grams, fat from about 1 to about 50 grams, caffeine from about 1 to about 600 milligrams, and 5-hydroxytryptophan (5-HTP) from about 1 to about 900 milligrams, to manage conditions associated with stress.

Bell teaches a nutritional supplement for use in weight maintenance in individuals who will undergo major surgery to prevent or reduce postoperative complications, see abstract. The nutritional supplement comprises approximately from about 10 to about 75 grams of carbohydrate, approximately from about 5 to 50 grams of protein, and approximately from about

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3 to about 30 grams of fat, see abstract. Bell teaches a nutritional supplement where the carbohydrate comprises fructose, see column 7, claim 6. Bell discloses a preferred embodiment, a nutritional supplement would contain carbohydrate having a low glycemic index, see column 3, lines 50-52. Bell teaches sources of protein can be whey protein, whey protein concentrate, and lactalbumin, column 4, lines 27-28 and 34. Bell discloses fats and oils such as vegetable oil, fish oil, or mixtures thereof, see column 4, lines 45 and 48. Bell teaches the nutritional supplement in the form of an extruded bar, or part of a food or beverage, see column 8, claim 15 and claim 16. Bell does not teach the nutritional supplement as comprising 5- hydroxytryptophan that aids in the relief of symptomology associated with stress.

Pollack teaches a dietary supplementation of both free and albumin bound tryptophan for increasing the production of serotonin in the brain, see column 2, lines 60-62. Pollack discloses that increased serotonin production can decrease or eliminate chronic pain, depression, insomnia, and appetite disorders, see column 2, lines 62 and 66-67. Pollack teaches the enzymatic steps necessary for the synthesis of serotonin (5-HT) from its natural precursor, tryptophan. The first step involves the conversion of tryptophan into 5-hydroxytryptophan (5-HTP) via interaction with the enzyme tryptophan hydroxylase. The second step involves the decarboxylation of 5-HTP into 5-HT via aromatic amino acid decarboxylase, see column 4, lines 1-7. Pollack discloses a method of converting tryptophan to 5-HTP using the addition of calcium to initiate the conversion of tryptophan to serotonin, see column 4 , lines 22-24.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have added the tryptophan plus calcium of Pollack to the nutritional supplement of Bell in order to reduce stress, as described by Bell, column 2, lines 36-37. While

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Bell does not specifically teach that the nutritional supplement can be separately assembled, used as a powder, or as part of a pharmaceutical composition, absent some evidence to the contrary, the nutritional supplement disclosed by Bell would inherently possess these properties.

Conclusion

All claims are rejected.

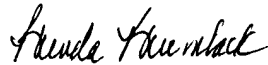
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday- Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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RT


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